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SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			CHIN, BRAD Y	
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			1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,355

Applicant(s)

HEHENBERGER ET AL.

Examiner

Brad Y. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/11/02, 1/21/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: On page 16, line 31, the word "entry" was used repetitively. It is believed the Applicant meant the following: "Errors may arise due to human error in entry of the sterilization process information". Appropriate correction is required.

Claim Objections

Claim 12 is objected to because of the following informalities: Applicant should replace "a report" with "the report". Proper antecedent basis was provided for in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-4, 6-7, 9-10, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kippenhan et. al., [U.S. Patent No. 6,485,979].

Regarding claim 1, Kippenhan teaches a method for:

receiving sterilization process information from a sterilization facility via a computer network (See Fig. 4; See Specification, col. 19, line 65 to col. 20, line 40);

generating a report based on the received information (See Specification, col. 20, lines 17-40 – provides a user with the ability to view a detailed account of information, such as sterilization process information, on the user's computer screen); and

providing a network client with access to the sterilization process information via the computer network (See Fig. 4, See Specification, col. 21, lines 30-35 & col. 22, lines 51-53).

Regarding claim 3, Kippenhan teaches a method where providing access to the report includes transmitting the report to the network client via the computer network (See Specification, col. 20, lines 12-16).

Regarding claim 4, Kippenhan teaches a method where providing access to the report includes serving a document containing the report upon request by the network client (See Specification, col. 19, line 65 to col. 21, line 67 – a user is provided access to a detailed account of information on his computer screen via the computer network when he requests such information from the computer network by logging onto and searching for such information).

Regarding claim 6, Kippenhan teaches a method where generating a report includes archiving the sterilization process information and generating the report based on the sterilization process information upon request by the network client (See Specification, col. 5, lines 26-39 – sterilization process information is stored in a storage medium, i.e. archived, where the sterilization process information is reported to the user on his computer screen via the computer network).

Regarding claim 7, Kippenhan teaches a method where generating a report includes arranging the sterilization process information to illustrate compliance with sterilization process standards (See Specification, col. 21, lines 52-67 – system provides user with sterilization process information illustrating appropriate sterilizer for compliance with sterilization process

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standards; See Specification, col. 22, lines 36-53 – system arranges sterilization process information to assist the user in properly performing sterilization procedures).

Regarding claim 9, Kippenhan teaches a method where generating a report includes identifying individual sterilization loads and load contents (See Specification, col. 21, lines 27-67; col. 22, lines 36-53 – the system provides the user access to information relating to the status of articles in the sterilization system, i.e. individual sterilization loads, sterilization packs and contents of the pack, load number etc.);

Regarding claim 10, Kippenhan teaches a method where the report includes sterilization processing characteristics for the individual sterilization loads, the sterilization processing characteristics for each load including at least one of type of sterilizer, sterilizer identification, cycle time, sterilization time, temperature, pressure, humidity, and sterilant concentration (See Specification, col. 22, lines 36-54 – user's computer screen for sterilization monitoring tracking system identifies a particular pack, i.e. load, to be subjected to the sterilization procedure and assists the user to correlate information from a sterilization indicator, i.e. type of sterilizer, sterilization identification, etc., with information relating to the particular items to be sterilized, i.e. particular parameters, such as temperature, pressure, humidity, and sterilant concentration, would be provided to correspond with the particular load to be sterilized).

Regarding claim 51, Kippenhan teaches a method for:

receiving sterilization process information from a sterilization facility via a computer network (See Fig. 4; See Specification, col. 19, line 65 to col. 20, line 40);

generating a cost report based on the received information (See Specification, col. 20, lines 17-40 – provides a user with the ability to view a detailed account of information, such as sterilization process information, on the user's computer screen; system improves cost management – management of sterilization process information and other information impacting

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cost is viewable as a detailed account of information or a report on the user's computer screen);
and

providing a network client with access to the sterilization process information via the computer network (See Fig. 4, See Specification, col. 21, lines 30-35 & col. 22, lines 51-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 2, 8, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of Swor et. al., [U.S. Patent No. 6,148,297]

Kippenhan teaches the method as defined in claim 1 above.

Kippenhan fails to teach that the network client (user) is associated with a reviewer that analyzes the report to evaluate compliance with sterilization process standards. Kippenhan further fails to teach that the network client is a regulatory agency or an audit organization.

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Kippenhan further fails to teach that the report includes integrating sterilization process information received from two or more of the sterilization facilities.

Swor et. al., [U.S. Patent No. 6,148,297]

Swor teaches each of the aspects identified above that Kippenhan fails to teach.

Regarding claim 2, Swor teaches a system and method where the network client (user) is associated with a reviewer that analyzes information to evaluate regulatory compliance (See claim 17 – the remote facility [user] comprises a regulatory agency [reviewer] with means for regulatory compliance).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the method of Swor because increased demands have been placed upon health information systems [including sterilization systems] to require extensive information dissemination, record-keeping, and report generation in compliance with regulatory standards (See Specification, col. 1, line 13-18). It would have been obvious to associate a reviewer (internal or external) with the network client (user) to analyze the sterilization process information received from sterilization facilities in monitoring regulatory compliance, i.e. sterilization process standards, which are usually set by regulatory agencies.

Regarding claim 8, Swor teaches a system and method where the network client (user) or remote facility is a regulatory agency or audit organization (See Specification, col. 3, lines 20-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan and Derzay with the method of Swor because, as indicated above, the requirement to comply with regulatory or industry standards creates the need for regulatory or governing agencies to have access to the information, in this case, sterilization process

information. It would have been obvious that the network client (user) could be a regulatory agency or an audit organization. This would provide the regulatory agency or audit organization with direct access to the information they are evaluating for regulatory compliance.

Regarding claims 11-12, Swor teaches a system and method for gathering and receiving information from multiple facilities.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the method of Swor for receiving information from multiple facilities because the use of a computer network not only allows multiple network clients (users) to access sterilization process information but it also allows multiple sterilization facilities to transmit sterilization process information. Accordingly, it would have been obvious to generate reports for the sterilization process information received from the multiple sterilization facilities (duplicating part for a multiple effect, See *In re Harza*, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960)). Additionally, it would have also been obvious to generate reports that integrate sterilization process information received from two or more of the sterilization facilities because the network client (user) may want to compare or evaluate information from multiple sterilization facilities, i.e. a regulatory agency may wish to compare sterilization process information from two or more sterilization facilities to identify trends or discrepancies with the information.

3. Claims 5, 18, 20-24, 26-27, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of Derzay et. al., [U.S. Patent No. 6,578,002].

Kippenhan teaches the method as defined above in claim 1. Kippenhan further teaches generating a cost report based on received information (See Specification col. 20, lines 17-40; See rationale for claim 51 above).

Kippenhan fails to teach a method where the document containing the report is a web page. Kippenhan further fails to teach a client computer, associated with a sterilization facility, that transmits sterilization process information via a computer network and a network server that receives the sterilization process information from the client computer via the computer network, generates a report based on the received information, and provides a network client with access to the report via the computer network.

Derzay et. al., [U.S. Patent No. 6,578,002]

Derzay teaches each of the aspects identified above that Kippenhan fails to teach.

Regarding claim 5, Derzay teaches (See Fig. 14) the method where providing access to the report includes serving a document (via a web page) containing the report upon request by the network client (web page 110; See Specification, col. 21, lines 6-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the network client (user) with access to the report by serving the document via a web page containing the report upon request by the network client because it is customary to provide or transmit information over the World-Wide Web. Providing access to the reported sterilization process information to a network client (user) via a website allows the user to access the information from multiple sites, including publicly accessible sites outside of the computer network.

Regarding claim 18, Derzay teaches a client computer (workstation 72 and field service units 24) that transmits information via a computer network and a network server (processing system 84 which may include one or a plurality of computers, as well as dedicated hardware or software servers) that receives the information from the client computer via the computer network ("proprietary or dedicated networks, as well as open networks"), generates a report

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based on the received information (system provides reported information on operating parameters, service histories, comparison of data, etc), and provides a network client with access to the report via the computer network, i.e. via the networks and client computer noted above (See Specification, col. 6, line 32 to col. 7, line 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the system and method of Derzay because transmission of information over the Internet or through a computer network commonly originates from a computer, in this case, from the computer of the sterilization facility, i.e. the client computer. Subsequently, network servers are commonly used with computer networks. Network servers function to receive transmitted information and process or store such information.

Regarding claim 20, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the network server to provide access to the report by transmitting the report to the network client via the computer network (See rationale for claims 3 and 18 above).

Regarding claim 21, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the network server to provide access to the report by serving a document containing the report upon request by the network client (See rationale for claim 4 and 18 above).

Regarding claim 22, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to provide access to the report by serving a document in the form of a web page containing the report upon request by network client (See rationale for claim 5, 18, and 21 above).

Regarding claim 23, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the network server to archive the sterilization process information and generate the report upon request by the network client (See rationale for claim 6 and 18 above).

Regarding claim 24, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to generate a report including arranging the sterilization process information to illustrate compliance with sterilization process standards (See rationale for claim 7 and 18 above).

Regarding claim 26, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to generate a report which identifies individual sterilization load and load contents (See rationale for claims 9 and 18 above).

Regarding claim 27, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to generate a report which includes sterilization processing characteristics for the individual sterilization loads, the sterilization processing characteristics for each load including at least one of type of sterilizer, sterilizer identification, cycle time, sterilization time, temperature, pressure, humidity, and sterilant concentration (See rationale for claims 10 and 18 above).

Regarding claim 52, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to generate such a report for cost management based on the received information and subsequently providing a network client with access to the report via the computer network (See rationale for claims 18 and 51 above).

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4. Claims 13-15 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of Guerindon et. al. [U.S. Patent No. 5,193,065].

Kippenhan teaches the method as defined in claim 1 above.

Kippenhan fails to teach a method further determining consumption of a quantity of sterilization material by the sterilization facility and processing an order for delivery of an additional quantity of the sterilization material to the sterilization based on the determination.

Kippenhan also fails to teach that the sterilization material, whose consumption is determined and replenished, includes at least one of sterilant, pack material, and indicators. The references also fail to teach a method further receiving an order for sterilization material from the sterilization facility and processing the order to direct delivery of the sterilization material to the sterilization facility.

Kippenhan also fails to teach the method comprising receiving sterilization process information from a sterilization facility via a computer network, determining consumption of a quantity of a sterilization material by the sterilization facility based on the sterilization process information, and processing an order for delivery of an additional quantity of the sterilization material to the sterilization facility based on the determination.

Guerindon, et. al., [U.S. Patent No. 5,193,065]

Guerindon teaches each of the aspects identified above that Kippenhan fails to teach.

Regarding claims 13 and 15, Guerindon teaches a system for requisitioning and distributing material in a manufacturing environment. Guerindon teaches a system that determines consumption of a quantity of material by a manufacturing facility; produces an electronic signal, which is received by the computer system (network), indicating that material has been depleted or consumed; and [the computer system (network)] processes an order for

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delivery of an additional quantity of the material to the facility based on the determination. (See Specification, col. 3, lines 29-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the method and system of Guerindon because managing a sterilization facility, or a manufacturing facility, requires managing costs and the efficiency of processes. In today's business e-commerce and Internet world, it would have been obvious to automate the supply and demand system of the sterilization facilities, contemplated in Kippenhan, with a method to determine consumption of sterilizing material by the sterilization facility or to receive orders for sterilization material from sterilization facilities and subsequently to replenish such sterilization material through an electronic, automated system as in Guerindon.

Regarding claim 14, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the sterilization material would at least the sterilant, pack material, or indicators. These materials are customary materials used in a sterilization facility and in sterilization processes as described in the method of Kippenhan (See Specification, col. 22, lines 36-46).

Regarding claim 35, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the method of Guerindon where sterilization process information is received, consumption of a quantity of sterilization material is determined, and an order for delivery of an additional quantity of the sterilization material is processed – a combination of claims 1 and 13 (See rationale for claim 13 above).

Regarding claim 36, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the method of Guerindon where sterilization process information is received, consumption of a quantity of sterilization material is

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determined, and an order for delivery of an additional quantity of the sterilization material is processed, where the sterilization material includes at least one of sterilant, pack material, and indicators – a combination of claims 1, 13, and 14 (See rationale for claim 14 above).

Regarding claim 37, Kippenhan further teaches that the sterilization material further includes electronic information for generation of a printed indicator and a method further comprising transmitting the electronic information to the client via the computer network (See Specification, col. 25, lines 30-52 – sterilization indicator is capable of providing information relating to the efficacy of the sterilization process which can be printed out as a bar code, further allowing for computer means for user access).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan, as defined above, with the method of Guerindon (See rationale for claim 13 above).

Regarding claim 38, Kippenhan further teaches that the sterilization material includes self-indicating ink and a method for further comprising delivering a quantity of the ink to the client (See Specification, col. 25, lines 1-14 – ink correlating means for correlating a pre-determined sterilization sensitive indicating ink to a sterilization procedure).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan, as defined above, with the method of Guerindon (See rationale for claim 13 above).

Regarding claim 39, Kippenhan teaches a method where the sterilization process information includes characteristics of a sterilization process, the method further comprising identifying a type of the sterilization material based on the characteristics of the sterilization process (See Specification, col. 24, lines 27-36).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan, as defined above, with the method of Guerindon (See rationale for claim 13 above).

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of McIlwaine et. al. [U.S. Patent No. 6,628,777].

Kippenhan teaches the method as defined in claim 1 above. Kippenhan further teaches providing access to information relating to sterilization materials and processes (See Specification, col. 21, lines 27-67).

Kippenhan fails to teach a method further providing interactive communication between technical personnel knowledgeable in sterilization processes and sterilization facility personnel.

McIlwaine et. al. [U.S. Patent No. 6,628,777]

McIlwaine teaches each of the aspects identified above that Kippenhan fails to teach.

McIlwaine teaches a system which provides interactive communication between technical personnel and customers or other constituents of an organization. McIlwaine further teaches a system that incorporates use of an e-mail help desk to provide technical support to employees and a web-based "chat" type system to provide information to sales prospects. McIlwaine further teaches a system that identifies use of Broadband communications to delivery video information to a broad range of constituents through contact centers. All of these systems identified in McIlwaine represent examples of managing customer communications and support through an interactive communication method between technical personnel knowledgeable in their respective field and external customers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the system and method of McIlwaine because, as with most electronic, automated information systems, technical support is customarily provided to the system's users. Because it is an objective of Kippenhan to utilize the efficiency and flexibility of network-based systems to manage, transfer, and monitor sterilization process information, a method for providing interactive technical support would be obvious.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan in view of Starnes et. al. [U.S. Patent Application Publication No. US 2002/0194014].

Kippenhan teaches the method as defined in claim 1 above.

Kippenhan fails to teach a method further accumulating information concerning best practices and trends in sterilization processing from multiple network clients and providing access to the best practices and trends information via the network.

Starnes et. al., [U.S. Patent Publication No. US 2002/0194014]

Starnes teaches each of the aspects identified above that Kippenhan fails to teach.

Starnes teaches an information management system and methods in which the host computer accumulates best practices information and trends of information from multiple sources and provides access to the best practice and trend information to users via a network (See Specification, p. 3, col. 2, [0037]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan with the system and method of Starnes because this would allow network clients (users) to learn of best practices of other sterilization facilities with relation to sterilization processes. It would also have been obvious because this information would provide

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sterilization facilities with trend information and industry standards supplied by regulatory agencies or audit organizations in evaluating their own policies and procedures utilized within their facilities.

7. Claims 19, 25, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18 above, and further in view of Swor.

Kippenhan and Derzay teach the method as defined in claim 18 above.

Regarding claim 19, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan and Derzay with the method of Swor, which teaches the association of a reviewer that analyzes the report to evaluate compliance with sterilization process standards (See rationale for claims 2 and 18 above).

Regarding claim 25, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan and Derzay with the method of Swor, which teaches that the network client is a regulatory agency or an audit organization (See rationale for claims 8 and 18 above).

Regarding claim 28, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan and Derzay with the method of Swor, which teaches a system and method for gathering and receiving information from multiple facilities.

It would have been obvious to provide a client computer, which includes multiple client computers that transmit sterilization process information for multiple sterilization facilities, and which the network server generates multiple reports for the multiple sterilization facilities because the client computer may represent a local area network (LAN) at the remote facilities, i.e. the sterilization facilities. Accordingly, this LAN would be transmitting sterilization process

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information to the network server, which would generate multiple reports for the multiple sterilization facilities (See rationale for claims 11 and 18 above).

Regarding claim 29, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan and Derzay with the method of Swor to generate reports that integrate sterilization process information received from two or more of the sterilization facilities because the network client (user) may want to compare or evaluate information from multiple sterilization facilities, i.e. a regulatory agency may wish to compare sterilization process information from two or more sterilization facilities to identify trends or discrepancies with the information (See rationale for claims 12 and 18 above).

8. Claims 30-32 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18 above, and further in view of Guerindon.

Kippenhan and Derzay teach the method as defined in claim 18 above.

Regarding claims 30 and 31, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to modify Kippenhan and Derzay with the method of Guerindon where the network server determines consumption of a quantity of a sterilization material by the sterilization facility, and process an order for delivery of an additional quantity of the sterilization material to the sterilization facility based on the determination, in which the sterilization material includes at least one of sterilant, pack material, and indicators (See rationale for claims 13, 14, and 18 above).

Regarding claim 32, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to modify Kippenhan and Derzay with the method of Guerindon where the network server receives an order for sterilization material from

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the sterilization facility, and process the order to direct delivery of the sterilization material to the sterilization facility (See rationale for claims 13, 15, and 18 above).

Regarding claims 40 and 41, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to modify Kippenhan and Derzay with the method of Guerindon where the network server determines consumption of a quantity of a sterilization material by the sterilization facility, and process an order for delivery of an additional quantity of the sterilization material to the sterilization facility based on the determination, in which the sterilization material includes at least one of sterilant, pack material, and indicators (See rationale for claims 13, 14, and 18 above).

Regarding claims 42-44, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to modify Kippenhan and Derzay with the method of Guerindon where the network server transmitted the electronic information for generation of a printed indicator to the client, processed an order for delivery of a quantity of the ink to the client, or identified a type of the sterilization material based on the characteristics of the sterilization process, as defined in claims 37-39 above, respectively (See rationale for claims 13 and 37-39 above).

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18 above, and further in view of McIlwaine.

Regarding claim 33, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to access information relating to sterilization materials, to access information relating to sterilization processes, and provide interactive communication between technical personnel knowledgeable in sterilization processes and sterilization facility personnel (See rationale for claims 16 and 18 above).

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan and Derzay as applied to claim 18 above, and further in view of Starnes.

Regarding claim 34, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious for the network server to accumulate information concerning best practices and trends in sterilization processing from multiple network clients and provide access to the best practices and trends information via the network (See rationale for claims 17 and 18 above).

11. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan, Guerindon, and Swor as applied to claim 35 above, and further in view of Brown, [U.S. Patent Application Publication No. US 2004/0098159].

Kippenhan and Guerindon teach the method of claim 35 above. Swor further teaches the method, which generates a report that indicates compliance with sterilization process standards based on the sterilization process information and further provides a reviewer with access to the report via the computer network (See claim 17 – the remote facility [user] comprises a regulatory agency [reviewer] with means for regulatory compliance).

Kippenhan, Guerindon, and Swor fail to teach that the method further includes scheduling maintenance for sterilization equipment associated with the sterilization facility based on the sterilization process information.

Brown, [U.S. Patent Application Publication No. US 2004/0098159]

Brown teaches each of the aspects identified above that Kippenhan, Guerindon, and Swor fail to teach.

Regarding claim 45, Brown teaches a method for scheduling maintenance for equipment associated with a facility based on the sterilization process information (See Specification, p. 8, col. 2, [0093] to p. 9, col. 1 [0093]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan, Guerindon, and Swor with the method of Brown because Brown identifies that the duration of unit operations is dependent on the volume processed. By determining the consumption of a quantity of sterilization material and tracking the processing of orders for delivery of additional quantity of sterilization material, scheduled maintenance can be determined based on the volume of sterilant or other sterilization materials processed or consumed. Accordingly, it would have been obvious to provide access to a reviewer to monitor reported information, such as consumption, processing, and scheduled maintenance, in reviewing compliance with sterilization process standards based on the aforementioned sterilization process information.

Regarding claim 46, it would have been obvious that the reviewer is a regulatory agency or an audit organization (See rationale for claims 8 and 45 above).

Regarding claim 47, as identified in claims 9 and 10 above, Kippenhan teaches a method where the report identifies sterilization load and load contents (See Specification, col. 21, lines 27-67; col. 22, lines 36-53 – see rationale for claim 9 above) and includes sterilization processing characteristics for the individual sterilization loads, the sterilization processing characteristics for each load including at least one of type of sterilizer, sterilizer identification, cycle time, sterilization time, temperature, pressure (See Specification, col. 22, lines 36-54 – see rationale for claim 10 above). Additionally, Kippenhan, Guerindon, Swor, and Brown teach the method of claim 45 above (See rationale for claim 45 above).

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12. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kippenhan, Derzay, Guerindon, as applied to claim 30 above, and further in view of Swor and Brown.

Kippenhan, Derzay, and Guerindon teach the method of claim 30 above; however, the references fail to teach a network server, which schedules maintenance for sterilization equipment associated with the sterilization facility based on the sterilization process information, generates a report that indicates compliance with sterilization process standards based on the sterilization process information, and provides a reviewer with access to the report via the computer network.

As identified in claim 2 above, Swor teaches the method, which generates a report that indicates compliance with sterilization process standards based on the sterilization process information and further provides a reviewer with access to the report via the computer network (See claim 17 – the remote facility [user] comprises a regulatory agency [reviewer] with means for regulatory compliance), as identified in the rationale for claim 45 above.

Brown teaches a method for scheduling maintenance for equipment associated with a facility based on the sterilization process information (See Specification, p. 8, col. 2, [0093] to p. 9, col. 1 [0093]).

Regarding claims 48, because it is common for network servers, as in Derzay, to manage computer networks, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kippenhan, Derzay, and Guerindon with the methods of Swor and Brown because Brown identifies that the duration of unit operations is dependent on the volume processed. By determining the consumption of a quantity of sterilization material and tracking the processing of orders for delivery of additional quantity of sterilization material, scheduled maintenance can be determined based on the volume of sterilant or other

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sterilization materials processed or consumed. Accordingly, it would have been obvious to include a method, which provides access to a reviewer to monitor reported information, such as consumption, processing, and scheduled maintenance, in reviewing compliance with sterilization process standards based on the aforementioned sterilization process information.

Regarding claim 49, it would have been obvious that the reviewer is a regulatory agency or an audit organization (See rationale for claims 8 and 46 above).

Regarding claim 50, as identified above, Kippenhan teaches a method where the report identifies sterilization load and load contents (See Specification, col. 21, lines 27-67; col. 22, lines 36-53 – see rationale for claim 9 above) and includes sterilization processing characteristics for the individual sterilization loads, the sterilization processing characteristics for each load including at least one of type of sterilizer, sterilizer identification, cycle time, sterilization time, temperature, pressure (See Specification, col. 22, lines 36-54 – see rationale for claim 10 above). Additionally, Kippenhan, Derzay, Guerindon, Swor, and Brown teach the method of claim 48 above (See rationale for claim 48 above).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

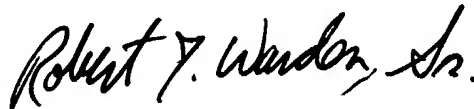
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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byc
October 22 2004

A handwritten signature in black ink that reads "Robert J. Warden, Sr." in a cursive style.

ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700